Attorney Docket No. 0450-0025,30

#### I. Amendments

The specification has been amended to claim the benefit of U.S. provisional application 60/117,846.

Claim 23 was amended to recite the step of correlating detected heteroduplex with the ability of administered antisense to reach and interact with c-myc mRNA in vessel cells.

No new matter has been added by this amendment.

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## II. Rejections under 35 U.S.C. §112, second paragraph

All of the claims in the application were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-22 have been cancelled. The specific rejection applied to claim 23 is respectfully traversed in view of the foregoing amendment and/or following remarks.

Claim 23, and claims 24 and 25 dependent thereon, were rejected as being incomplete for omitting an essential step, which is the correlation or recapitulation step at the end of the claim restating the objective of the preamble.

Claim 23, as now amended, restates the step that correlates the method with the objective of the method.

In view of the claim amendments and foregoing remarks with respect thereto, the applicant submits that the claims now pending in the application meet the requirements of 35 U.S. C. §112, second paragraph. Accordingly, it is requested that the rejections be withdrawn.

# III. Rejections under 35 U.S.C. §102(e)

Claim 1, 6-10, 16 and 22 are rejected under 35 U.S.C. §102(e) as being anticipated by Zalewski et al. All of these claims have been cancelled by this amendment.

# IV. Rejections under 35 U.S.C. §103

Claims 1-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kalewski et al. in view of Kobayashi et al., Summerton et al., and Agrawal et al.

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By this amendment, all of these claims have been cancelled.

In view of the foregoing, the applicant submits that the claims pending in the application are now in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 324-0880.

Respectfully submitted,

Peter J. Dehlinger

Registration No. 28,006

Date: <u>6-4-20</u>0)

Correspondence Address:

Customer No. 22918 Phone: (650) 324-0880

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Attorney Docket No. 0450-0025.30

Appl. No. 09/493,427

# VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

This application [is a continuation-in-part application of] claims priority to U.S. provisional application for "Non-Invasive Method for Detecting Target RNA", SN 60/117,846, filed January 29, 1999, which is incorporated by reference into the present application.

In the Claims:

23. (Amended) In a method aimed at reducing the risk of restenosis in a region of a patient's coronary vessel which has been treated by coronary angioplasty using a catheter with a distal-end expandable balloon, by administering to the vessel region, an antisense compound directed against a target human *c-myc* mRNA sequence, a method for assaying the ability of the antisense compound to reach and interact with *c-myc* mRNA in vessel cells, comprising

administering to the patient, a morpholino antisense compound having a substantially uncharged backbone, and a sequence that spans the start codon of the human *c-myc* gene,

at a selected time after said administering, taking a sample of a body fluid from the subject, [and]

detecting in said sample the presence of a nuclease-resistant heteroduplex composed of the antisense compound and the target RNA region[.] and

correlating the presence of detected heteroduplex in said sample with the ability of said antisence compound to reach and interact with c-myc mRNA in vessel cells.

# Law Group

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Docket No. 0450-0025.30 Ref. USSN 09/493,427 filed 1/29/00

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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING TRANSMITTED VIA TELEFACSIMILE TO (703) 305-3014, THE UNITED STATES PATENT AND TRADEMARK OFFICE, WASHINGTON, D.C., ON:

Dat:

facsimile is for informational purposes only.

This amendment and associated documents are being mailed via First Class Mail to the U.S. Patent and Trademark Office on this date (6/4/01). This copy via

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C., 20231, on:

Date: June 4, 2001

Attorney Docket No.: 0450-0025.30

Applicant: Patrick L. Iversen

Serial No.: 09/493,427

Filing Date: January 29, 2000

For: Antibense Restenosis Composition

AND METHOD

FAX RECEIVED

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GROUP 1600

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

- 1. Transmitted herewith are the following:
  - An Amendment Under 37 CFR §1.111
  - A Petition for 3-Month Extension of Time
  - Sequence Listing printout, floppy diskette, matching declaration
- 2. Entity Status
  - Small Entity Status (37 CFR §1.9 and §1.27) has been established by a previously submitted Small Entity Statement.
- 3. Conditional Petition for Extension of Time:
  An Extension of Time is requested to provide for timely filing if necessary for timely filing of this transmittal and enclosures.
- 4. Provisional Fee Authorization
  Please charge any underpayment in fees for timely filing of this transmittal and enclosures to Deposit Account No. 04-0531.

Respectfully submitted,

Date: 6-4-2001

Peter J. Dehlinger

Registration No. 28,006

Correspondence Address:

Customer No. 22918 Phone: (650) 324-0880

Attorney Docket No. 0450-0025.30

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C., 20231, on:

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Iversen and Weller

SERIAL No.: 09/493,427

FILED: January 29, 2000

FOR: ANTISENSE RESTENOSIS COMPOSITION

AND METHOD

EXAMINER: Epps

ART UNIT:

1635

## Declaration Under 37 CFR §1.821

Assistant Commissioner for Patents Washington, D.C. 20231

Śir:

- I, Peter J. Dehlinger, declare and affirm as follows:
- I am an agent for the applicant.
- The floppy disc which accompanies this Declaration contains the required sequence listing.
- The sequence listing recorded on said disc matches the hard copy of the sequence listing accompanying this Declaration.
- The present submission contains no new matter relative to the application as originally filed.

Repspectfully submitted,

Reter J. Dehlinger

Registration No. 28,00%

Correspondence Address;

Customer No. 22918